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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/241,455	02/02/1999	NIKOLAI M. KRIVITSKI		8764

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/241,455	KRIVITSKI, NIKOLAI M.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,9-19,22 and 24-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *16-19,25-29 and 39-42* is/are allowed.

6)☒ Claim(s) *2-6,9-15,22,24 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102 & 35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 15, 22, 24, 32, 33, 35, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt ('234).

Alt discloses a multi-lumen, multi-parameter catheter and further disclose a dilution indicator source; a catheter connectable to the dilution indicator source, the catheter having surgical revision means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream sensor a fixed distance from the indicator port for producing a signal corresponding to passage of the dilution indicator external to the catheter; a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor; a catheter; a temperature gradient generator on the catheter located to alter a blood parameter external to the catheter; means for

effecting a corrective procedure; a blood parameter sensor connected to the catheter and spaced at a fixed distance from the temperature gradient generator to sense the altered blood parameter external to the catheter and provide a signal determining a blood flow; a controller connectable to the temperature gradient generator and the blood parameter sensor to calculate the blood flow; the sensor detects one of electrical impedance and electrical resistance; the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood; the indicator source connected to the catheter for providing a known rate and volume of dilution indicator source to the indicator introduction port; and the volume of indicator source is one of a bolus and a constant infusion. See Column 5, lines 65-68; Column 6, lines 1-12 and 52-68; Column 7, lines 1-12; and Column 8, lines 8-32.

4. Claims 15, 32, 33, 35, 37 and 38 rejected under 35 U.S.C. 102(b) as being anticipated by Degironimo et al.

Degironimo et al disclose an injection system and further disclose a dilution indicator source; a catheter connectable to the dilution indicator source, the catheter having surgical revision means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream sensor a fixed distance from the indicator port for producing a signal corresponding to passage of the dilution indicator external to the catheter; a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor; the sensor detects one of electrical impedance and electrical resistance; the sensor detects one of an optical, thermal, electrical,

chemical or physical property of the blood; the indicator source connected to the catheter for providing a known rate and volume of dilution indicator source to the indicator introduction port; and the volume of indicator source is one of a bolus and a constant infusion. See Column 3, lines 26-68; Column 4, lines 1-10; Column 6, lines 7-25.

Even though Degironimo et al discloses the use of the balloon for stabilizing the catheter in the heart and not for a corrective vascular procedure, the current claim language constitutes an intended use of the balloon, and therefore the balloon or surgical revision means merely has to be capable of performing the intended use of performing a corrective procedure. It is well known in the art that a balloon on a catheter can be used to anchor and stabilize the catheter as well as perform a stenosis reducing procedure.

5. Claims 2-6, 9-14, 30, 31, 34 and 36 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Quinn et al ('654).

Quinn et al disclose a thermodilution catheter and further disclose a catheter body having a stenosis reducing member selectively actuateable to reduce a stenosis in a vessel; one of a local heat source and a local heat sink affixed to the catheter body for inducing a blood property change to blood flowing external to the stenosis reducing catheter, the one of local heat source and local heat sink located at a fixed distance form the stenosis reducing member; a sensor affixed to the catheter body and spaced at a given distance from the local heat source and local heat sink for providing a signal

corresponding to a change in a blood property external to the stenosis reducing catheter; a controller operably connected to the sensor to calculate the flow rate corresponding to the signal from the downstream sensor; a port that includes and aperture for introducing a blood property variant; the port and sensor are spaced apart; the sensor detects changes in one of electrical impedance and electrical resistance; the sensor detects one of an optical, electrical, chemical or physical property of the blood; a local temperature gradient generator; one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects; and the volume of indicator is one of a bolus and a constant infusion. See Column 3, lines 25-35 and 48-63; Column 4, lines 25-31 and 60-67; Column 5, lines 1-7 and 26-49; and Column 6, lines 35-44.

Even though Quinn et al discloses the use of a balloon for stabilizing the catheter in the heart and not for a corrective vascular procedure, it would have been obvious to one of ordinary skill in the art to utilize the same balloon for a corrective procedure since it is well known in the art that balloons placed on catheters are used for stabilizing or anchoring the catheter in the vasculature, as well as for reducing a stenosis even though the design of the balloon remains essentially constant.

Allowable Subject Matter

6. The following is a statement of reasons for the indication of allowable subject matter: Claims 16-19, 25-29 and 39-42 are allowable since no prior art could be found teaching or suggesting a method for monitoring blood flow during a vascular corrective

procedure comprising: reducing the stenosis; and determining at a controller connected to the indicator source and the sensor a change in blood flow past the downstream sensor.

Response to Arguments

7. Applicant's arguments, filed March 29, 2004, with respect to the rejection(s)of claim(s) 22 and 24 under Quinn et al ('654) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Alt ('234).

8. Applicant's arguments filed March 29, 2004 have been fully considered but they are not persuasive. Degironimo et al still discloses the claimed subject matter of claims 15, 32, 33, 35, 37 and 38 because the current claim language constitutes an intended use of the structure of the claimed element. The amended Claims 15 and 35 now constitute an intended use of the claimed surgical revision means, and no longer can be thought of as a means plus function recitation because the claimed element is no longer merely "a means for" performing a function once it was amended to become "surgical revision means for" performing a corrective procedure. Degironimo et al discloses the use of a balloon for stabilizing the catheter. As discussed above, one of ordinary skill in the art would still be able to use a centering balloon to reduce a stenosis in a blood vessel. Furthermore, Degironimo et al does not disclose or suggest the material of the centering balloon. Therefore, the balloon of Degironimo et al is still capable of performing a vascular corrective procedure because when the balloon is inflated, the

balloon would be capable of reducing a stenosed region of the vasculature, due the lack of disclosure pertaining to the type of material the balloon is constructed.

Likewise, the disclosure of Quinn et al still discloses the claimed subject matter of 2, 3, 9-14, 30, 31, 34 and 36 due to similar reasons set forth above regarding the intended use of the claimed element as well as the lack of disclosure of the material of the balloon on the catheter. Even though Quinn et al do not explicitly disclose the use of the balloon for reducing a stenosis, the balloon is still capable of performing a stenosis reducing procedure.

9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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